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| 10/570,231   | 02/28/2006  | Meng Hsin Chen       | 21524Y              | 7529             |
| 210 7590 03/21/2008<br>MERCK AND CO., INC<br>P O BOX 2000<br>RAHWAY, NJ 07065-0907 |             |                      |                     |                  |
| EXAMINER<br>NOLAN, JASON MICHAEL   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1626   |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/570,231

**Applicant(s)**

CHEN ET AL.

**Examiner**

JASON M. NOLAN

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 9-12 and 14 is/are rejected.
- 7) ☒ Claim(s) 6, 13, 15 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S5108)  
Paper No(s)/Mail Date 02/28/2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Office Action is responsive to Applicants Transmittal of New Application, filed **02/28/2006**. **Claims 1-16** are pending.

#### *Information Disclosure Statement*

Applicants' information disclosure statement (IDS), filed on **02/28/2006** has been considered. Please refer to Applicants' copy of the 1449 submitted herein.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1-5 & 7** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds wherein the variable **Het/Ar = pyridine**, does not reasonably provide enablement for compounds wherein **Het/Ar = any and/or all C<sub>6-10</sub> aryl or C<sub>3-10</sub> heterocycle**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A conclusion of lack of enablement means that, based on

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the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:

- (A) *The breadth of the claims;*
- (B) *The nature of the invention;*
- (C) *The state of the prior art;*
- (D) *The level of one of ordinary skill;*
- (E) *The level of predictability in the art;*
- (F) *The amount of direction provided by the inventor;*
- (G) *The existence of working examples; and*
- (H) *The quantity of experimentation needed to make or use the invention based on the content of the disclosure.*

***The breadth of the claims - The nature of the invention***

**Claims 1-5 & 7** are drawn to compounds according to formula I, wherein the definitions of **R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, R<sub>5</sub>, R<sup>e</sup>, X, Q, Y, Z, etc.** are defined therein. Compounds according to these formulae are potentially useful as pharmaceuticals.

***The state of the prior art***

A search encompassing the compounds of formula I shows that the art is not so advanced such that the claims can include a scope as broad as **Het/Ar = any and/or all C<sub>6-10</sub> aryls or C<sub>3-10</sub> heterocycles**. The Examiner points out that upon review of a comprehensive search, only compounds wherein **Het/Ar = pyridine** (the instant application) are known in the art. Therefore, in order for Applicant to claim any and/or

all C<sub>6-10</sub> aryls or C<sub>3-10</sub> heterocycles, there must be guidance (support) in the specification in order to enable one of skill in the art to make and use this invention as claimed.

***The level of predictability in the art***

The elemental substitution of any aryl or heterocycle for **pyridine** in an organic compound changes the necessary starting materials for making these compounds as well as the reactivity of said starting materials. The elemental difference influences the bond length, electronegativity, and therefore the localization of electrons with respect to the core functionality. Therefore, it is unpredictable to know, from the outlined examples in the instant specification, how to make all of the compounds as claimed in formula I.

***The amount of direction provided by the inventor***

The instant specification is not seen to provide adequate guidance, which would allow the skilled artisan to extrapolate from the disclosure and examples provided, to make the claimed compounds commensurate in the scope with the instant claims. There is a lack of information pertaining to the synthesis of any compound according to formula I, except for when **Het/Ar = pyridine**.

***The existence of working examples***

The working examples set forth in the instant specification are directed to the compounds of formula I, in which **Het/Ar = pyridine**. There has not been provided sufficient evidence that would warrant the skilled artisan to accept the synthetic

examples provided in the specification as correlative proof that any compound of formula I would indeed be able to be synthesized using the methods as outlined.

***The quantity of experimentation needed to make and use the invention based on the content of the disclosure***

Indeed, in view of the information set forth supra, the instant disclosure is not seen to be sufficient to enable the preparation of any compound of formula I wherein **Het/Ar = any and/or all C<sub>6-10</sub> aryl or C<sub>3-10</sub> heterocycle**. One skilled in the art could not use the entire scope of the claimed invention without undue experimentation. One skilled in the art would be confronted with an undue burden of experimentation to acquire alternative starting materials in view of formula I AND attempt to prepare the desired products with no guarantee of success. Furthermore, one skilled in the art would be confronted with an undue burden of experimentation to isolate, characterize, and test the various compounds of formula I.

***Claim Rejections - 35 USC §§ 101 & 112***

**Claims 9-12** provides for *the use of* compounds of the formula I, but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

**Claims 9-12** are rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 15** is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the claim, after "a prostaglandin" is recited the phrase: "or derivative thereof," and the scope of this term is unclear such that it fails to define the metes and bounds of its limitation. A chemical derivative can mean several things; for example: isomer, stereoisomer, prodrug, salt, etc. Examiner suggests the use of a more descriptive term or terms such as the specific examples in **Claim 16**.

### ***Claim Objections***

**Claims 6, 13, 14, & 16** are objected to as being dependent upon a rejected base **Claim 1**, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Allowable Subject Matter***

**Claim 8** is in condition for allowance.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is [Jason.Nolan@uspto.gov](mailto:Jason.Nolan@uspto.gov). The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M<sup>c</sup>Kane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jason M. Nolan, Ph.D./

Examiner, Art Unit 1626

/Joseph K McKane/

Supervisory Patent Examiner, Art Unit 1626